REMARKS:

Applicant acknowledges the Examiner's reconsideration of the restriction requirement and appreciates the decision to reduce the number of Groups.

Claims 38-39 (dependant), 70 (independent), 71-72 (dependant) and 79 (dependant) have been cancelled without prejudice or disclaimer. Claims 81-85 (dependant) have been added. Claims 18-20, 25-29, 65-69, 73-78 and 80-85 are pending.

Specification Objections

In the specification, a new paragraph has been added at page 1 to indicate that the application claims priority to an earlier application, U.S. Application Ser. No. 09/374,367, which was copending at the time this application was filed and has at least one common inventor.

Claim Objections

At paragraph 5 of the Detailed Action, the Examiner has objected to the claims for being dependant upon non elected claims. The objection has been obviated by rewriting Claims 18, 19, 25, 65, and 75 in independent form.

Claim Rejections

35 U.S.C. §112

35 U.S.C. §112, second paragraph

Claims 18-20, 25-29, 65-74 have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite because the Examiner contends that the phrases "molecular weight of about 78 kDa to about 120 kDa" or "molecular weight of about 76 kDa to about 213 kDa" are not clear. The applicant disagrees; however to expedite prosecution, the claims have been amended to

recite "a monoclonal antibody, deposited under ATCC designation number PTA-450, or antigen binding fragment thereof." In view of the presently amended claims, withdrawal of the rejection is requested.

35 U.S.C. §112, first paragraph

Claims 19-20, 25-29, 75-80 have been rejected under 35 U.S.C. §112, first paragraph, because as Examiner states, at paragraph 9 of the Detailed Action, that "the specification does not provide evidence that the claimed biological materials are (1) known and readily available to the public; (2) reproducible from the written description". It is submitted that the accompanying statement of the applicant satisfactorily evidences that "the claimed biological materials are (1) known and readily available to the public; and (2) reproducible from the written description." As suggested by the Examiner, we have enclosed a declaration by the applicant and a statement from the ATCC depository. This documentation was previously filed in the related U.S. Application Ser. No. 09/374,367. Accordingly, withdrawal of the §112, first paragraph rejections is respectfully requested.

Claims 18-20, 25-29, 65-80 also have been rejected under 35 U.S.C. §112, first paragraph. In paragraph 10 of the Detailed Action, the Examiner argues that the specification "does not reasonably provide enablement for a method of inhibiting the growth of myeloma or ovarian tumor cells with an antibody that binds an antigen characterized in that the antigen has a molecular weight of about 78 kDa to about 120 kDa." With respect to the Examiner's contention regarding the nature of the antigen and the various antibodies that could bind to the antigen, the applicant disagrees. However to expedite prosecution, the claims have been amended to recite "a monoclonal antibody, deposited under ATCC designation number PTA-450, or antigen binding fragment thereof."

The Examiner further contends that "one cannot extrapolate the teaching of the specification to the claimed invention because there is no guidance on or exemplification of any correlation between in vitro data an *in vivo* for inhibiting tumor growth." Page 11-12 of Detailed Action. The Examiner continues that based on the data presented in the specification, "it could not be predicted that, in the *in vivo* environment, the antibodies would be used for treatment of cancer." Page 13 of the Detailed Action.

Applicant traverses this ground of rejection. Applicant believes that the teachings of the specification combined with the know-how and skill possessed by the skilled practitioner in the pertinent art, *e.g.*, monoclonal antibody therapeutics, allow the practice of the claimed methods for therapeutic purposes. It is submitted that at the time of the filing, a person skilled in the art would have a reasonable expectation that the antibodies disclosed in the specification could be used to treat multiple myeloma or ovarian cancer without undue experimentation. A correlation between binding of a monoclonal antibody and its ability to reduce tumor size and increase survival had been reported in the art as of the filing date of the application. For example, Ozaki et al. (copy enclosed) report that an unconjugated monoclonal antibody that detects a human plasma cell-specific antigen (HM1.24) has an antitumor effect *in vivo* against human myeloma xenografts in mice. Ozaki et al. state that "In mice bearing advanced tumors, multiple injections of anti-HM1.24 MoAb reduced the tumor size and significantly prolonged survival, including tumor cure, in a dose-dependant manner." *See* Ozaki et al., "Immunotherapy of Multiple Myeloma With a Monoclonal Antibody Directed Against a Plasma Cell-Specific Antigen, HM1.24" *Blood*, 90:3179-86 (1997) at abstract. Ozaki et al. conclude that "anti-HM1.24 MoAb can be used for immunotherapy of multiple myeloma and related plasma cell dyscrasias." *See id.* at abstract; *see also id.* at page 3179, 1st column, 3rd paragraph. Therefore, at the time this application was filed, one skilled in the art would

have a reasonable basis to conclude that an antibody that was specific for an antigen on a particular tumor cell would be useful in inhibiting the growth of or killing that tumor cell.

Applicant confirmed this expectation with her work published in the publication Krueger et al., "Monoclonal Antibody Identifies a Distinctive Epitope Expressed by Human Multiple Myeloma Cells" *Journal of Immunotherapy* 24(4):334-44 (2001) (copy enclosed). Applicant demonstrates that the monoclonal antibody VAC69, which is disclosed in the specification, does trigger cancer-specific cytotoxicity *in vivo* using mice transplanted with human myeloma. Krueger et al. reports that the monoclonal antibody VAC69 triggers cancer-specific cytotoxicity *in vitro* in the presence of complement as well as *in vivo* in sever combined immunodeficiency model transplanted with human multiple myeloma. *See* Krueger et al. at abstract; *see also id.* at page 342 at Figure 4 and Table 2. The antibody provoked tumor cell killing in its native form without the need for a conjugated toxin. *See id.* at 2nd column, 1st paragraph. Accordingly, one skilled in the art would reasonably expect to be able to practice the claimed invention without undue experimentation.

Claims 18-20, 25-29, and 65-74 have been rejected under 35 U.S.C. §112, first paragraph. The Examiner states, in paragraph 11, that the claims contain "subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention." The applicant disagrees; however to expedite prosecution, the claims have been amended to recite "a monoclonal antibody, deposited under ATCC designation number PTA-450, or antigen binding fragment thereof." In view of the presently amended claims, withdrawal of this rejection is requested.

35 U.S.C. §102

Claims 18, 65 and 70 have been rejected under 35 U.S.C. §102(b) as being anticipated by Lloyd et al. (1997, *Int'l. J. Cancer*, 71:842-850). The applicant disagrees. However to expedite prosecution, the claims have been amended to recite "a monoclonal antibody, deposited under ATCC designation number PTA-450, or antigen binding fragment thereof." In view of the presently amended claims, withdrawal of this rejection is requested.

35 U.S.C. §103(a)

Claims 18-20, 25-26 and 65-74 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Lloyd et al. (1997, *Int'l. J. Cancer*, 71:842-850), and further in view of Harlow et el. (1988, *Antibodies, A Laboratory Manual, Cold Spring Harbor Laboratory*, pp. 319-329, 626-631). The applicant disagrees. However to expedite prosecution, the claims have been amended to recite "a monoclonal antibody, deposited under ATCC designation number PTA-450, or antigen binding fragment thereof." In view of the presently amended claims, withdrawal of this rejection is requested.

AUTHORIZATION

The applicant has enclosed herewith all fees believed to be properly assessable in this application. However, should additional fees be required by the filing of these papers, the Commissioner is hereby authorized to charge any additional fees, or to credit any overpayment, to Deposit Account No. 13-4500, Order No. 3828-4000US1.

CONCLUSION

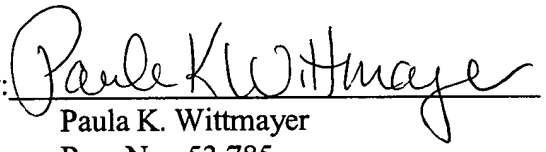
Applicant respectfully believes that the claims of the subject application are now in condition for allowance. An action passing this case to issue is courteously urged.

In the event that the Examiner is of the opinion that further discussion of the application would be helpful, the Examiner is hereby respectfully requested to telephone the applicant's undersigned representative at (212) 415-8787 and is assured of full cooperation in an effort to advance the prosecution of the instant application and claims to allowance.

Respectfully submitted,

MORGAN & FINNEGAN, L.L.P.

Date: May 10, 2004

By: 
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